LARSEN & TOUBRO LIMITED

Powai Works, Saki Vihar Road, P. O. Box 8901, Mumbai-400 072 • Tel. : 858 1401 / 11

Ref :

E-mail :

25th April, 2004

510(K) SUMMARY

(Per section 807.92 ©)

CONTACT DATA			
Submitter's Name		Larsen & Toubro Limited	
Address		KIADB Industrial Area, Hebbal Hootagalli, Mysore – 570018, Karnataka, INDIA	
Telephone	91-821-2402561	**Fax**	91-821-2402468
Contact Person	A.B.Deshpande	**Title**	Head – Quality Assurance
E-Mail address		DeshpandeAB@myw.ltindia.com	
Date the summary was prepared		April 25th,2004	

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DEVICE	
Trade name	STELLAR 404
Common name	Patient Monitoring System
Classification name	Vital Signs Monitor

PREDICATE DEVICE IDENTIFICATION			
CFR21 Section	870.2300	**Product code (optional)**	MWI
Classification panel		Cardiovascular	
Device Class		Class II	
Legally marketed Comparison Device / K#		• PLANET patient Monitoring System (L&T Medical Equipments & systems) / K032871	

K042560
p. 3/4

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DEVICE DESCRIPTION

This STELLAR 404 unit is a 2 parameter Patient monitor System (TFT color monitor) with NIBP and Pulse oximetry with an optional inbuilt two channel thermal array recorder for printing of Tabular trends & waveforms.
STELLAR 404 has waveform display capability for Plethysmograph. It also displays the digital values of PR, SpO_2 and Non-Invasive Blood Pressure (Systolic, Diastolic and Mean) readings. It has graded and color coded alarms It has 2 hours and 12 hours tabular and graphical trends for SpO_2. It has special tabular trend for NIBP to store the last 100 readings. Alarm recall feature offers last 16 alarm conditions.

INTENDED USE OF THE DEVICE

The STELLAR 404 2 parameter Patient Monitoring system is intended to monitor a single adult, pediatric or neonatal patient's vital signs at the bedside or during intra-hospital transport along with the appropriate accessories mentioned / supplied with the unit. Vital signs parameter includes Plethysmograph. It can also display the digital values of PR, SpO_2, Non-Invasive Blood Pressure (Systolic, Diastolic and Mean) readings.
The user, responsible to interpret the monitored data made available, will be a professional health care provider. The device, which can also be used as a portable device, permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. The monitor is not intended for home use.

10

K042360
p 4/4

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TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

Device : Larsen & Toubro limited make STELLAR 404 Patient Monitoring System.

Predicate device:

PLANET patient Monitoring System (Make: L&T Medical Equipments & systems) / K032871

The parameters available with the Larsen & Toubro Limited make STELLAR 404 Patient monitoring system (NIBP and Pulse oximetry) are also available with the predicate device. The range and accuracy of the parameters & method of sensing are similar to the predicate devices. In STELLAR 404 monitor audible & visual alarms are provided similar to that in the Predicate device.

STELLAR 404 has got TFT color display like PLANET. STELLAR 404 has got thermal array recorder similar to that available in PLANET. Weight of the STELLAR 404 (4Kg maximum) is less than that of the predicate device. Battery provided in STELLAR 404 is Lithium ion, where as it is Lead acid battery in case of predicate device PLANET.

Comparison of all the parameters of STELLAR 404 to that of the predicate devices is given in the "Substantial Equivalence Equipment comparison" document.

Compliance to standards:

The following international standards are referred.
IEC 60601-1 Medical Electrical safety
IEC 60601-1-2 EMC compliance

Conclusion:

Based on the Technological characteristics of STELLAR 404 and its comparison with that of predicate device PLANET, Larsen & Toubro Limited believes that their device is substantially equivalent to this predicate Monitor and doesn't pose any additional risk on safety & effectiveness of the device.

(Mohan G.R)
Head – Design & Development

11

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 - 2004

Larsen & Toubro Ltd.
c/o Mr. Ned Devine
Entela, Inc.
3033 Madison Ave. SE
Grand Rapids, MI 49548

Re: K042560
Trade Name: STELLAR 404 Patient Monitoring System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: September 21, 2004
Received: September 21, 2004

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042560

Device Name: STELLAR 404

Indications for Use:

The STELLAR 404 two parameter Patient Monitoring System is intended to monitor a single adult, pediatric or neonatal patient's vital signs at the bedside or during hospital transport along with the appropriate accessories mentioned/ supplied with the unit. Vital signs parameter includes Plethysmograph. It can also display the digital values of PR, SpO_2, Non-Invasive Blood Pressure (Systolic, Diastolic and Mean) readings.

The user, responsible to interpret the monitored data made available, will be a professional health-care provider. The device, which can also be used as a portable device, permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. The monitor is not intended for home use.

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042560

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)